

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

MITSUBISHI TANABE PHARMA
CORPORATION, JANSSEN
PHARMACEUTICALS, INC., JANSSEN
PHARMACEUTICA NV, JANSSEN
RESEARCH AND DEVELOPMENT, LLC,
and CILAG GMBH INTERNATIONAL,

Plaintiffs,

v.

AUROBINDO PHARMA USA, INC., *et al.*,

Defendants.

Civil Action No. 17-5005 (RMB)(JS)
(consolidated)

Return Date: July 20, 2020

CONFIDENTIAL – FILED UNDER
SEAL

ORAL ARGUMENT REQUESTED

Document Filed Electronically

**BRIEF IN SUPPORT OF DEFENDANTS ZYDUS PHARMACEUTICALS (USA) INC.,
MSN LABORATORIES PRIVATE LTD., AND MSN PHARMACEUTICALS, INC.'S
APPEAL FROM AND OBJECTIONS TO THE MAGISTRATE JUDGE'S
MAY 18, 2020 ORDER DENYING DEFENDANTS' MOTION TO STRIKE
PLAINTIFFS' EXPERT REPORTS (ECF NO. 316)**

Jay R. Deshmukh (jdeshmukh@kasowitz.com)
Hershy Stern (hstern@kasowitz.com)
Jayita Guhaniyogi, Ph.D.
(jguhaniyogi@kasowitz.com)
KASOWITZ BENSON TORRES LLP
1633 Broadway
New York, NY 10019
Tel. (212) 506-1700
Fax. (212) 500-3580
Attorneys for Defendant
Zydus Pharmaceuticals (USA) Inc.

George C. Lombardi
WINSTON & STRAWN
35 W. Wacker Drive
Chicago, IL 60611
(312) 558-6600

Sean R. Kelly (skelly@saiber.com)
Katherine A. Escanlar (kae@saiber.com)
SAIBER LLC
18 Columbia Turnpike, Suite 200
Florham Park, New Jersey 07932
Telephone: (973) 622-3333
Facsimile: (973) 622-3465
Attorneys for Defendant
Zydus Pharmaceuticals (USA) Inc.

James S. Richter (jrichter@midlige-richter.com)
MIDLIGE RICHTER, LLC
645 Martinsville Road
Basking Ridge, NJ 07820
(908) 626-0622
Attorneys for Defendants MSN Laboratories

glombardi@winston.com

Private Ltd. and MSN Pharmaceuticals, Inc.

Jovial Wong (jwong@winston.com)

Sharon Lin (slin@winston.com)

WINSTON & STRAWN

1901 L. St. NW

Washington, DC 20036

(202) 282-5000

Attorneys for Defendants MSN Laboratories

Private Ltd. and MSN Pharmaceuticals, Inc.

TABLE OF CONTENTS

I.	INTRODUCTION	1
II.	FACTUAL AND PROCEDURAL BACKGROUND.....	4
A.	The Patent-In-Suit.....	4
B.	Plaintiffs' Infringement Contentions Disclosed They Intended To Prove Infringement Using Only Standard XRPD Testing.	5
C.	Plaintiffs Doubled Down On Their Sole Reliance On XRPD In Interrogatory Responses.....	7
D.	Plaintiffs Repeatedly Refused To Produce Samples Of Their Purported Commercial Embodiment, Stating They Were Not "Relevant to Any Claim"	8
E.	Plaintiffs' Expert Reports	9
F.	The Motion To Strike And The Magistrate Judge's Decision.....	12
III.	LEGAL STANDARDS	12
A.	The Magistrate's Decision Should Be Reviewed <i>De Novo</i>	12
B.	Expert Reports Should Be Stricken When They Rely On New Theories Of Infringement Not Disclosed During Discovery	13
IV.	THE MAGISTRATE JUDGE'S ORDER DENYING DEFENDANTS' MOTION SHOULD BE REVERSED AND PLAINTIFFS' EXPERT REPORTS SHOULD BE STRICKEN.....	16
A.	The Magistrate Judge Erred By Denying Defendants' Motion To Strike The Portion Of Plaintiffs' Reports That Relyed On The Janssen Product.....	16
1.	The Local Rules Discourage Trial By Surprise	17
2.	Plaintiffs' Late Production Of Samples – They Previously Refused to Produce – Is Not Equivalent To Disclosure Of Their Infringement Theories.....	18
B.	The Magistrate Judge Erred When He Did Not Strike The Portion Of Plaintiffs' Expert Reports That Relyed On Undisclosed Testing Methodologies.....	20
1.	Disclosure of Plaintiffs' Contentions Would Not Reveal Work Product	21

2.	Defendants Could Not Have Challenged Plaintiffs' Expert Reports Before The Reports Were Served	24
C.	Defendants Have Been Prejudiced by Plaintiffs' Failure To Timely Disclose Their Infringement Theories, Contrary To The Magistrate Judge's Erroneous Finding.	25
V.	CONCLUSION.....	30

TABLE OF AUTHORITIES

	Page(s)
Cases	
<i>Adobe Sys. Inc. v. Wowza Media Sys.</i> , No. 11-CV-02243-JST, 2014 WL 709865 (N.D. Cal. Feb. 23, 2014).....	25
<i>Berger v. Rossignol Ski Co., Inc.</i> , No. C 05-02523 CRB, 2006 WL 1095914 (N.D. Cal. Apr. 25, 2006)	2, 15, 17
<i>Computer Acceleration Corp. v. Microsoft Corp.</i> , 503 F. Supp. 2d 819 (E.D. Tex. 2007).....	14
<i>Connectel, LLC v. Cisco Sys., Inc.</i> , 391 F. Supp. 2d 526 (E.D. Tex. 2005).....	15
<i>Crouse v. Allegheny Cty.</i> , No. 09-01221, 2016 WL 6086066 (W.D. Pa. Jan. 25, 2016)	13
<i>Dome Petroleum Ltd. v. Emp’rs Mut. Liab. Ins. Co. of Wis.</i> , 131 F.R.D. 63 (D.N.J. 1990).....	13
<i>Eisai Co. v. Teva Pharm. USA, Inc.</i> , 629 F. Supp. 2d 416 (D.N.J. 2009)	12
<i>Galderma Labs., L.P. v. Amneal Pharms., LLC</i> , No. 16-207-LPS, 2018 WL 508876 (D. Del. Jan. 22, 2018)	25, 27, 29
<i>Golden Hour Data Sys., Inc. v. Health Servs. Integration, Inc.</i> , No. C 06-7477 SI, 2008 WL 2622794 (N.D. Cal. July 1, 2008)	27
<i>Gunter v. Ridgewood Energy Corp.</i> , 32 F. Supp. 2d 162 (D.N.J. 1998)	13, 18
<i>Howmedica Osteonics Corp. v. Depuy Orthopaedics, Inc.</i> , No. 11-6498 (SDW), 2014 WL 6675923 (D.N.J. Nov. 24, 2014)	14
<i>Intellectual Ventures I LLC v. AT&T Mobility LLC</i> , No. CV 13-1668-LPS, 2017 WL 658469 (D. Del. Feb. 14, 2017)	15, 22, 23
<i>Karl Storz Endoscopy-Am., Inc. v. Stryker Corp.</i> , No. 14-CV-00876-RS(JSC), 2017 WL 3873622 (N.D. Cal. Sept. 5, 2017).....	14
<i>Kimberly-Clark Worldwide, Inc. v. First Quality Baby Prod., LLC</i> , No. 1:CV-09-1685, 2010 WL 4537002 (M.D. Pa. Nov. 3, 2010)	23

<i>King Pharm., Inc. v. Sandoz Inc.</i> , No. CIV.A. 08-5974 (GEB), 2010 WL 2015258 (D.N.J. May 20, 2010), <i>appeal denied, judgment aff'd</i> , 2010 WL 4789950 (D.N.J. Sept. 8, 2010)	2, 16, 19
<i>M. Eagles Tool Warehouse, Inc. v. Fisher Tooling Co.</i> , No. 97-1568-(JAG), 2007 WL 979854 (D.N.J. Mar. 30, 2007)	13, 24
<i>Mercedes Benz USA LLC v. Coast Auto. Grp. Ltd.</i> , No. 99-3121 (WHW), 2008 WL 4378294 (D.N.J. Sept. 23, 2008)	13
<i>Merck Sharp & Dohme Corp. v. Sandoz, Inc.</i> , No. 12-3289 (PGS)(LHG), 2014 WL 997532 (D.N.J. Jan. 6, 2014)	3, 14
<i>MLC Intellectual Property, LLC v. Micron Technology, Inc.</i> , 14-cv-03657-SI, 2019 WL 1865921 (N.D. Cal. 2019)	15, 22
<i>N.L.R.B. v. Frazier</i> , 966 F.2d 812 (3d Cir. 1992).....	12
<i>Phigenix, Inc. v. Genentech, Inc.</i> , 783 F. App'x 1014 (Fed. Cir. 2019)	14, 15, 18, 25
<i>Read v. Profeta</i> , 397 F. Supp. 3d 597 (D.N.J. 2019)	13, 20, 24
<i>Shared Memory Graphics LLC v. Apple, Inc.</i> , 812 F. Supp. 2d 1022 (N.D. Cal. 2010)	15, 18
<i>Tessanderlo Kerley, Inc. v. OR-Cal, Inc.</i> , No. C 11-04100 WHA, 2012 WL 1253178 (N.D. Cal. Apr. 13, 2012)	23
<i>Tillotson Corp. v. Shijiazhuang Hongray Plastic Prod., Ltd.</i> , 244 F.R.D. 683 (N.D. Ga. 2007).....	23
<i>Voxpath RS, LLC v. LG Elecs. U.S.A., Inc.</i> , No. 2:12-CV-952 DMC-MF, 2012 WL 5818143 (D.N.J. Nov. 14, 2012)	14
<i>Zenith Labs., Inc. v. Bristol-Myers Squibb Co.</i> , 19 F.3d 1418 (Fed. Cir. 1994).....	17
Statutes	
21 U.S.C. §355(j)(5)(B)(iii).....	29
28 U.S.C. § 636(b)(1)(A)	12
Rules	
Fed. R. Civ. P. 26(e)	13

Fed. R. Civ. P. 37(c)(1).....	<i>passim</i>
Fed. R. Civ. P. 72.....	1, 12, 26
L. Civ. R. 72.1(c)(1).....	1, 12
L. Pat. R. 3.1	2, 5, 15, 23
L. Pat. R. 3.2	2, 17

Defendants Zydus Pharmaceuticals (USA), Inc. (“Zydus”) and MSN Laboratories Private Ltd. and MSN Pharmaceuticals Inc. (collectively, “MSN,” and, together with Zydus, “Defendants”) submit this brief in support of their appeal, pursuant to Fed. R. Civ. P. 72(a) and L. Civ. R. 72.1(c)(1)(A), of Magistrate Judge Schneider’s May 18, 2020 Order (“Order”), ECF No. 316, as memorialized in the transcript of proceedings dated May 18, 2020 (ECF No. 321 (“Transcript” or “Tr.”)), which denied Defendants’ motion to strike certain portions of the infringement expert reports served on February 7, 2020 (the “Expert Reports” or “Reports”) offered by Plaintiffs Mitsubishi Tanabe Pharma Corporation (“Mitsubishi”), Janssen Pharmaceuticals, Inc., Janssen Pharmaceutica NV, Janssen Research and Development, LLC (collectively “Janssen”), and Cilag GmbH International (“Cilag” and, with Mitsubishi and Janssen, “Plaintiffs.”)

I. INTRODUCTION

After years of discovery and disclosures, Plaintiffs’ Expert Reports introduced, for the very first time, several new theories of infringement (the “New Infringement Theories”) that had not been disclosed in their infringement contentions or interrogatory responses. Specifically, the Reports newly disclosed that Plaintiffs now plan to rely on a comparison between the accused products and Janssen’s own purported commercial embodiment (the “Janssen Product”) – even though Plaintiffs repeatedly asserted that the Janssen Product was “not relevant” to Plaintiffs’ claims. The Reports also revealed that Plaintiffs intend to rely on four testing methodologies that were not previously disclosed: ¹⁹F ssNMR testing, polarized light microscopy, Raman spectroscopy, and synchrotron-XRPD testing (the “New Methodologies”), despite the fact that their infringement contentions disclosed only one type of test (standard XRPD).

Plaintiffs were required to crystallize and disclose their infringement theories early in the case to avoid trial by surprise. L. Pat. R. 3.1; *King Pharm., Inc. v. Sandoz Inc.*, No. CIV.A. 08-5974 (GEB), 2010 WL 2015258, at *4 (D.N.J. May 20, 2010) (the Local Patent Rules are “designed to require parties to crystallize their theories of the case early in the litigation and to adhere to those theories once they have been disclosed.”), *appeal denied, judgment aff’d*, 2010 WL 4789950 (D.N.J. Sept. 8, 2010). And Rule 37(c)(1) specifies that materials not disclosed during discovery may not be used at trial. Fed. R. Civ. Pro. 37(c)(1). As a result of Plaintiffs’ refusal to timely disclose the New Infringement Theories, Defendants have been denied fair notice of Plaintiffs’ claims, and incurably prejudiced in preparing their defense. Accordingly, Defendants filed their Motion to Strike the portions of Plaintiffs’ Expert Reports that rely on these New Infringement Theories.

The Magistrate Judge’s denial of Defendants’ motion was clearly erroneous, contrary to law, and should be reversed. The Magistrate improperly dismissed Plaintiffs’ new comparison to the Janssen Product because cases “evolve.” But an “evolving” theory is exactly what the Rules are designed to avoid. *See King Pharm.*, 2010 WL 2015258, at *4 (denying motion to amend contentions.) Further, although Plaintiffs repeatedly refused to produce samples of the Janssen Product because they were “not relevant” to the case, the Magistrate mistakenly found that by producing the samples “in the spirit of compromise,” Plaintiffs somehow disclosed that the Janssen Product was relevant. The Local Patent Rules provide for a method of disclosing infringement theories – in infringement contentions pursuant to Local Patent Rule 3.2 – and Defendants should not have to read between the lines of what Plaintiffs do or do not produce in discovery to try to surmise what Plaintiffs’ contentions are. *Cf. Berger v. Rossignol Ski Co., Inc.*, No. C 05-02523 CRB, 2006 WL 1095914, at *3 (N.D. Cal. Apr. 25, 2006) (noting that

infringement contentions are intended to prevent “vexatious shuffling of positions”).¹ Indeed, the Magistrate, in striking portions of Defendants’ invalidity expert report, stated that “plaintiffs should not have to go through what the Court calls ‘hoops and loops’ and inferences to identify defendants’ defenses,” and the same standard should be applied in this instance. (Ex. DD at 9:21-24.)²

The Magistrate Judge also erroneously found that Plaintiffs’ infringement contentions adequately disclosed their New Infringement Theories (despite only referencing XRPD testing), in part based upon the determination that further disclosure would violate the work product doctrine. But the law clearly holds that the work-product doctrine does not prohibit disclosure of infringement contentions, including details about testing. Moreover, as a factual and practical matter, Plaintiffs’ disclosure that they intended to rely on unidentified “testing,” did not disclose that they intended to use the New Methodologies. If plaintiffs are permitted to say, simply, that “testing will show” infringement, that would render the Local Patent Rules toothless. Plaintiffs should be held to the infringement theory that they did disclose in their contentions.

The Magistrate also concluded that Defendants unjustifiably delayed seeking the Court’s assistance, because Defendants did not earlier move to compel more detail regarding the “testing” referenced in Plaintiffs’ infringement contentions. But Defendants are not challenging the infringement contentions – which disclosed that Plaintiffs intended to prove infringement using XRPD testing. Rather, Defendants are challenging the Expert Reports, which added the

¹ New Jersey courts have favorably cited to California and Texas case law interpreting analogous local patent rules as persuasive authority. See, e.g., *Merck Sharp & Dohme Corp. v. Sandoz, Inc.*, No. 12-3289 (PGS)(LHG), 2014 WL 997532, at *3 n.2 (D.N.J. Jan. 6, 2014) (“The Court’s decision is informed by districts with analogous local patent rules, such as the Northern District of California and the Eastern District of Texas.”).

² All citations to “Ex. ___” refer to exhibits to the June 23, 2020 Declaration of Sean Kelly in support of this appeal, concurrently filed.

New Infringement Theories, including the comparison to the Janssen Product and the New Methodologies and go well beyond what was earlier disclosed. Defendants only learned on February 7, 2020, when Plaintiffs served their Reports, that Plaintiffs intended to rely on infringement theories not previously disclosed in their contentions, and promptly filed their motion after the parties were unable to reach a resolution.

Finally, the Magistrate Judge materially misapprehended the facts and misapplied the law when he found that Defendants have suffered no prejudice. As multiple courts have recognized, the ability to cross-examine witnesses at deposition or trial is no remedy for Defendants' inability to address Plaintiffs' true Infringement Contentions throughout discovery.

In light of Plaintiffs' failure to comply with the Local Patent Rules, Zydus and MSN respectfully request that the Court reverse and vacate the Order of United States Magistrate Judge Joel Schneider, dated May 18, 2020 (ECF No. 316), and strike those portions of Plaintiffs' Expert Infringement Reports that use or rely on the New Infringement Theories.

II. FACTUAL AND PROCEDURAL BACKGROUND

A. The Patent-In-Suit

Plaintiffs allege that Defendants infringed claim 3 of U.S. Pat. No. 7,943,582 ("the '582 patent") by filing applications with the FDA to market generic versions of Plaintiffs' Invokana® (canagliflozin) (Zydus and MSN) and Invokamet® (canagliflozin/metformin HCl) (Zydus).³

The '582 patent purportedly teaches a hemihydrate crystal form of canagliflozin and its characteristic features. Claim 3 of the '582 patent is dependent on claim 1:

³ Plaintiffs originally asserted claims 1, 3-4, and 6-7 from the '582 patent and claims 1 and 3-5 of U.S. Patent No. 8,513,202 ("the '202 patent"), but now assert only claim 3 of the '582 patent. (See Ex. K (emails confirming withdrawal of claims asserted against Zydus and MSN).)

1. A crystalline form of 1-(β -D-glucopyranosyl)-4-methyl-3-[5-(4-fluorophenyl)-2-thienylmethyl]benzene hemihydrate.

3. A crystalline form of 1-(β -D-glucopyranosyl)-4-methyl-3-[5-(4-fluorophenyl)-2-thienylmethyl]benzene hemihydrate of claim 1, having substantially the same X-ray diffraction pattern as set out in FIG. 1.

(Ex. L, '582 patent, claims 1, 3.) "1-(β -D-glucopyranosyl)-4-methyl-3-[5-(4-fluorophenyl)-2-thienylmethyl]benzene" is also known as canagliflozin.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]⁴

B. Plaintiffs' Infringement Contentions Disclosed They Intended To Prove Infringement Using Only Standard XRPD Testing.

Plaintiffs served their infringement contentions on June 29, 2018 against Zydus and MSN (together the "Infringement Contentions"), pursuant to Local Patent Rule 3.1. (Ex. M; Ex. N.)

Both Infringement Contentions are similar. [REDACTED]

[REDACTED]

[REDACTED]



(Ex. M, p. 10-11; Ex. N, p. 8.) The only testing methodology mentioned in these Contentions was “X-ray diffraction,” also called “XRPD.”⁵ (Ex. M-N.) Plaintiffs did not disclose that they would rely on any comparison between Plaintiffs’ purported commercial embodiment or products (the Janssen Product) and the Zydus or MSN Accused Products. Nor did Plaintiffs disclose using the New Methodologies, which are just four of dozens of different types of tests that could be used to identify and distinguish polymorphic forms of canagliflozin.⁶

Plaintiffs have had samples of Zydus’ Accused Products since April 26, 2018. (Ex. O at ¶ 11); Ex. P at ¶ 11.) And Plaintiffs have had samples of MSN’s canagliflozin API and tablets

⁵ Conventional XRPD is distinct from synchrotron-XRPD, the testing methodology used by Drs. Gozzo and Behets. Synchrotron-XRPD requires access to a specialized facility with a high energy synchrotron radiation source (*see* Exs. C, E, H, J) and, unlike conventional XRPD that involves low energy X-ray source, is not referenced in the ’582 Patent (*see* Ex. L).

⁶ Plaintiffs have admitted that there are dozens of such tests. Defendants’ fourth joint interrogatory asked Plaintiffs to identify tests “the analytical testing Plaintiffs contend is the most appropriate to identify and distinguish among” forms of canagliflozin. In its supplemental response, Plaintiffs cited over 40 documents, which in turn disclosed over twenty different testing methodologies, including mass spectrometry, elemental analysis, Fourier Transform IR, UV visible spectroscopy, ¹H solution NMR, ¹³C solution NMR, HPLC analysis, ¹⁹F ssNMR, conventional XRPD, synchrotron XRPD, near Infra-Red (NIR), Fourier Transform Infra Red (FTIR), optical microscopy, Differential Scanning Calorimetry (DSC), Thermogravimetric Analysis (TGA), ¹³C ssNMR, Dynamic Vapor Sorption (DVS), UV spectroscopy, hot stage pXRD, single crystal XRD, scanning electron microscopy, Raman spectroscopy, as well as water content testing. (Ex. EE at 8; *see e.g.* Ex. NN (JSN-INV-00018311 at 14-23, 26; JSN-INV-00037113 at 3-4, 5-9; JSN-INV-00348422-34 at 348424, at 348425, 348426, 348427-28; JSN-INV-00402846-59 at 402853; JSN-INV-00037116 at 2, 6-7, JSN-INV-00051853 at 3-11; JSN-INV-00051872 at 4, 6; JSN-INV-00037240 at 3-19).

since October 18, 2017. (Ex. Q at ¶ 11; Ex. R at ¶ 11.) In the almost two years between serving their Contentions and Expert Reports, Plaintiffs did not attempt to amend or supplement the Infringement Contentions, even after they received samples of the Accused Products and began performing some of the undisclosed testing methodologies (for example, Plaintiffs appear to have performed ¹⁹F ssNMR testing in 2018, *see* Ex. U).

C. Plaintiffs Doubled Down On Their Sole Reliance On XRPD In Interrogatory Responses

Plaintiffs had an additional opportunity to disclose their New Infringement Theories in interrogatory responses. Zydus's First Set of Interrogatories, served on July 18, 2018, requested

[REDACTED]

[REDACTED]

Identify, with reference to specific chemical analytical methods, the “testing of Zydus’s ANDA products and the canagliflozin [REDACTED]

[REDACTED]
including all settings, parameters, and conditions of analysis required to perform such testing, whether such testing has been performed, and if so the results of any such testing that form the basis for said contention.

(Ex. S, Interrogatory No. 3.) In response, Plaintiffs identified no additional testing methods, nor did they disclose that they planned to compare Zydus's products to the Janssen Product. (Ex. T at 7-8.) Notably, as of the date of Plaintiffs' response, August 28, 2018, Plaintiffs appear to have in fact already completed ¹⁹F ssNMR tests (*see* Ex. U – raw data from Dr. Munson's ¹⁹F ssNMR providing testing date of May 1, 2018).

MSN also specifically sought further information from Plaintiffs regarding the tests that they claimed in their Infringement Contentions would support their allegations:

Describe in detail the factual bases for Plaintiffs' contention that MSN's ANDA Products and/or the canagliflozin active pharmaceutical ingredient ("API") used therein "contain a crystalline form of canagliflozin hemihydrate," including but not limited to the results of any testing of MSN's ANDA Products and the canagliflozin API used to make MSN's ANDA Products.

(See Ex. V, MSN's First Set of Interrogatories to Plaintiffs, served March 15, 2019, No. 1.) In response, Plaintiffs provided no substantive information, and certainly did not identify any of the New Infringement Theories. (Ex. W, Plaintiffs' Objections and Responses to MSN's First Set of Interrogatories, dated April 15, 2019.) As of the date of Plaintiffs' response, Plaintiffs appeared to have in fact already completed at least synchrotron testing of MSN's Accused Products. (Ex. J, Behets MSN Report at ¶ 20.)

Fact discovery closed on August 7, 2019, and Plaintiffs never updated their Interrogatory Responses or Infringement Contentions to reflect their New Infringement Theories.

D. Plaintiffs Repeatedly Refused To Produce Samples Of Their Purported Commercial Embodiment, Stating They Were Not "Relevant to Any Claim"

Defendants first sought samples of Plaintiffs' purposed commercial embodiment of the '582 patent in early 2018. (Ex. FF, Nos. 116-23.) Defendants requested samples of both Plaintiffs' marketed products, [REDACTED]

[REDACTED] In response, Plaintiffs refused to produce any samples, stating that they were "not relevant to any claim or defense currently in this action and not proportional to the needs of the case." (Ex. GG.)

These requests were discussed during a meet and confer in September 2018. Plaintiffs reiterated their earlier refusal to produce samples, maintaining that they "[would] not produce samples as those samples are neither relevant to any claim or defense currently in this action, nor proportional to the needs of the case." (Ex. HH at 1.) After months of dispute and several letters, including to the Court (Exs. II, JJ), in November of 2019 Plaintiffs finally agreed to

produce samples, although they made no reference to the relevance (or irrelevance) of the samples:

In the spirit of compromise and to reduce the number of disputes and the burden on the Court, Plaintiffs will produce a sample of canagliflozin hemihydrate that Plaintiffs contend fall within the scope one or more claims of the patents-in-suit regardless of whether one or more of Plaintiffs' experts rely on it.

(Ex. KK.)

Plaintiffs produced their samples in the latter part of December 2019, a year and half after Plaintiffs served their Infringement Contentions and approximately four months after the close of fact discovery. (Ex. LL (email discussing shipping dated Dec. 18, 2019).) A mere month and a half later, Plaintiffs served their Expert Reports, several of which heavily relied on the testing of Janssen's samples in an attempt to show infringement – the same samples that Plaintiffs claimed were irrelevant to this case for almost two years.

E. Plaintiffs' Expert Reports

Plaintiffs served their opening infringement Expert Reports on February 7, 2020. In those reports, Plaintiffs for the first time disclosed several New Infringement Theories, well beyond what had been disclosed in the Infringement Contentions.

To Defendants' surprise, Plaintiffs disclosed for the first time in the Reports that they intend to rely on comparisons between the Accused Products and the Janssen Product to show infringement, despite having heavily disputed the relevance of that Product just a few months earlier. For example, Plaintiffs' expert Dr. Munson tested the Accused Products using

¹⁹FssNMR and compared those results to Janssen's earlier internal ¹⁹FssNMR tests of its own crystalline canagliflozin hemihydrate samples. Relying on Dr. Munson's new comparison theory of infringement, Dr. Trout opines that the Accused Products infringe. (Ex. A at ¶¶ 125-32, 150-54; Ex. F at ¶¶ 150-54; Ex. B at ¶¶ 72-73, 100-02, 141, 149, 153, 157; Ex. G at ¶¶ 71-73, 98-106,

140-41, 149.) Dr. Trout also relies on Dr. Blatter's analysis of the Janssen Product by Raman spectroscopy and polarized light spectroscopy to conclude that Defendants' Accused Products infringe. (Ex. D at ¶¶ 56-61; Ex. I at ¶¶ 60-69.)

Nowhere did Plaintiffs' prior Contentions or Interrogatory Response disclose this New Infringement Theory, nor did they disclose the documents reflecting Janssen's internal testing of its Products, which Plaintiffs experts also relied on. (Ex. BB.)

The Reports also disclosed – for the very first time – that Plaintiffs were relying on New Methodologies, namely ¹⁹F ssNMR testing, polarized light microscopy, Raman spectroscopy, and synchrotron-XRPD testing, and associated infringement theories that were not disclosed or even hinted at in Plaintiffs' Infringement Contentions. Plaintiffs required *five different experts* (plus a sixth expert whose report is not implicated here), located across the globe, to run all of the various tests. (See Ex. B at ¶¶ 1, 87-96; Ex. C at ¶¶ 1, 10; Ex. D at ¶¶ 1, 15; Ex. E at ¶¶ 1, 13; Ex. G at ¶¶ 1, 85-94; Ex. H at ¶¶ 1, 10; Ex. I at ¶¶ 1, 15; Ex. J at ¶¶ 1, 13.)

The portions of Plaintiffs expert reports that rely on the New Infringement Theories are summarized below:

Report	Specific Portion(s)	Bases
Opening Expert Report of Eric J. Munson, Ph.D. to Zydus ("Munson Zydus Report"), Ex. B.	All paragraphs of the Munson Zydus and MSN Reports, and all exhibits.	<ul style="list-style-type: none"> • ¹⁹F ssNMR testing is not disclosed in Plaintiffs' Infringement Contentions • Relies on comparisons with Janssen samples
Opening Expert Report of Eric J. Munson, Ph.D. to MSN ("Munson MSN Report"), Ex. G.		
Opening Expert Report of Fabia Gozzo, Ph.D. to Zydus ("Gozzo Zydus Report"), Ex. C.	All paragraphs of the Gozzo Zydus and MSN Reports, and all exhibits.	<ul style="list-style-type: none"> • Synchrotron-XRPD testing is not disclosed in Plaintiffs' Infringement Contentions

Report	Specific Portion(s)	Bases
Opening Expert Report of Fabia Gozzo, Ph.D. to MSN (“Gozzo MSN Report”), Ex. H.		
Opening Expert Report of Geert Behets, Ph.D. to Zydus (“Behets Zydus Report”), Ex. E.	All paragraphs of the Behets Zydus and MSN Reports, and all exhibits.	<ul style="list-style-type: none"> • Synchrotron-XRPD testing is not disclosed in Plaintiffs’ Infringement Contentions
Opening Expert Report of Geert Behets, Ph.D. to MSN (“Behets MSN Report”), Ex. J.		
Opening Expert Report of Fritz Blatter, Ph.D. to Zydus (“Blatter Zydus Report”), Ex. D.	All paragraphs of the Blatter Zydus and MSN Report, and all exhibits.	<ul style="list-style-type: none"> • Polarized light microscopy and Raman spectroscopy are not disclosed in Plaintiffs’ Infringement Contentions
Opening Expert Report of Fritz Blatter, Ph.D. to MSN (“Blatter MSN Report”), Ex. I.		<ul style="list-style-type: none"> • Relies on comparisons with Janssen samples
Opening Infringement Expert Report of Bernhardt Trout, Ph.D. to Zydus (“Trout Zydus Report”), Ex. A.	<ul style="list-style-type: none"> • ¶¶ 77, 80-86, 90-91, 93-103, 105-111, Exs. 15-17 of Zydus Munson Report. 	<ul style="list-style-type: none"> • Relies on documents not disclosed in Plaintiffs’ Infringement Contentions
Opening Infringement Expert Report of Bernhardt L. Trout, Ph.D. to MSN (“Trout MSN Report”), Ex. F.	<ul style="list-style-type: none"> • ¶¶ 77, 80-86, 89-90, 92-95, 96-102, 104-110, Exs. 15-17 of MSN Trout Report. 	
	<ul style="list-style-type: none"> • ¶¶ 112-132, 136-144, 150-154, Exs. 22-64 of Zydus Munson Report. • ¶¶ 89-90, 111-138, 142-154, Exs. 22-41 of MSN Munson Report. 	<ul style="list-style-type: none"> • Relies on testing methodologies performed by Dr. Munson, Dr. Gozzo, Dr. Behets, and Dr. Blatter, which were not disclosed in Plaintiffs’ Infringement Contentions as explained above • Relies on comparisons with Janssen samples

F. The Motion To Strike And The Magistrate Judge's Decision

On February 26, 2020, Zydus and MSN separately requested that Plaintiffs withdraw any new theories that were not previously disclosed. (Ex. X; Ex. Y.) The parties held a meet and confer call, and Plaintiffs then responded by letter disputing Zydus's and MSN's positions. (Ex. Z; Ex. AA.) Because Plaintiffs refused to withdraw any of their expert reports or sections thereof, Zydus and MSN sought relief from the Magistrate Judge to enforce the Local Patent Rules and avoid unfair prejudice to Zydus and MSN as they defend themselves in this action.

After briefing and oral arguments, Magistrate Judge Schneider denied Defendants' motion to strike. In relevant part, the Magistrate determined: (a) Plaintiffs' Infringement Contentions adequately disclosed their infringement theories; (b) Defendants delayed seeking relief; and (c) Defendants were not prejudiced by Plaintiffs' failure to disclose their infringement theories. (Ex. OO, Tr. at 39:10-40:5; 42:16-43:18.) However, as shown in detail below, the Magistrate Judge's denial of Defendants' motion was clearly erroneous, contrary to law, and should be reversed and vacated.

III. LEGAL STANDARDS

A. The Magistrate's Decision Should Be Reviewed *De Novo*

Because Defendants' motion, if granted, strikes large parts of Plaintiffs' infringement case, the Court should review the Magistrate Judge's order *de novo*, pursuant to Fed. R. Civ. P. 72. See *N.L.R.B. v. Frazier*, 966 F.2d 812, 815-16 (3d Cir. 1992) (holding that if a matter "more closely resembles" a dispositive motion, "the district court should employ de novo review").

If this Court determines that the Order is non-dispositive, the legal conclusions therein still require do novo review. See, e.g., *Eisai Co. v. Teva Pharm. USA, Inc.*, 629 F. Supp. 2d 416, 424 (D.N.J. 2009) ("While a magistrate judge's decision typically is entitled to deference, a magistrate judge's legal conclusions on a non-dispositive motion will be reviewed de novo.").

And even if this Court decides to apply a more deferential standard of review, the findings below are still “clearly erroneous or contrary to law.” 28 U.S.C. § 636(b)(1)(A); *see also* Fed. R. Civ. P. 72(a); L. Civ. R. 72.1(c)(1). “[A] finding is clearly erroneous when although there is evidence to support it, the reviewing court on the entire evidence is left with the definite and firm conviction that a mistake has been committed.” *Dome Petroleum Ltd. v. Emp’rs Mut. Liab. Ins. Co. of Wis.*, 131 F.R.D. 63, 65 (D.N.J. 1990) (internal quotation marks and citation omitted). A ruling is contrary to law if the magistrate has misinterpreted or misapplied applicable law. *See Gunter v. Ridgewood Energy Corp.*, 32 F. Supp. 2d 162, 164 (D.N.J. 1998).

B. Expert Reports Should Be Stricken When They Rely On New Theories Of Infringement Not Disclosed During Discovery

Federal Rule 37(c)(1) provides that if a party fails to disclose information during discovery, or timely supplement or correct discovery disclosures with updated information, that information must be excluded at trial:

If a party fails to provide information . . . as required by Rule 26(a) or (e), the party is not allowed to use that information . . . to supply evidence on a motion, at a hearing, or at a trial, unless the failure was substantially justified or is harmless.

Fed. R. Civ. P. 37(c)(1). “Rule 37 is written in mandatory terms and is designed to provide a strong inducement for disclosure of Rule 26(a) material.” *Mercedes Benz USA LLC v. Coast Auto. Grp. Ltd.*, No. 99–3121 (WHW), 2008 WL 4378294, at *2 (D.N.J. Sept. 23, 2008) (citing *Newman v. GHS Osteopathic, Inc., Parkview Hosp. Div.*, 60 F.3d 153, 156 (3d Cir. 1995)); *see also M. Eagles Tool Warehouse, Inc. v. Fisher Tooling Co.*, No. 97–1568–(JAG), 2007 WL 979854, at *12 (D.N.J. Mar. 30, 2007) (Rule 37 provides “‘self-executing,’ ‘automatic’ sanction to ‘provide [] a strong inducement for disclosure of material’”). Excluding evidence at trial as a sanction for failure to disclose under Rule 26(e) in a timely fashion is “automatic,” unless the party can show the violation is either “substantially justified or harmless.” *M. Eagles Tool*

Warehouse, Inc., 2007 WL 979854, at *12. The party trying to stave off such an “automatic” penalty has the burden to show that its failure was substantially justified or harmless. *See, e.g., Read v. Profeta*, 397 F. Supp. 3d 597, 648-49 (D.N.J. 2019); *Crouse v. Allegheny Cty.*, No. 09-01221, 2016 WL 6086066, at *3 (W.D. Pa. Jan. 25, 2016).

In addition, in patent cases such as this, litigants must abide by the Local Patent Rules. The Patent Rules “exist to further the goal of full, timely discovery and provide all parties with adequate notice and information with which to litigate their cases.” *Voxpath RS, LLC v. LG Elecs. U.S.A., Inc.*, No. 2:12-CV-952 DMC-MF, 2012 WL 5818143, at *3 (D.N.J. Nov. 14, 2012); *Computer Acceleration Corp. v. Microsoft Corp.*, 503 F. Supp. 2d 819, 822 (E.D. Tex. 2007)). Accordingly, the Rules “force [] adversaries to disclose, solidify, and adhere to their legal theories of infringement and invalidity in the early stages of the litigation.” *Howmedica Osteonics Corp. v. Depuy Orthopaedics, Inc.*, No. 11-6498 (SDW), 2014 WL 6675923, at *4 (D.N.J. Nov. 24, 2014); *see also Voxpath RS*, 2012 WL 5818143, at *3 (quoting *Integrated Circuit Sys., Inc. v. Realtek Semiconductor Co.*, 308 F. Supp. 2d 1106, 1107 (N.D. Cal. 2004)) (the purpose of the Rules is to “ensure litigants put all their cards on the table up front”); *Merck Sharp & Dohme Corp. v. Sandoz, Inc.*, No. 12-3289 (PGS)(LHG), 2014 WL 997532, at *3, *9 (D.N.J. Jan. 6, 2014) (precluding amendment and noting that “the Rules require the ‘ultra early disclosure of infringement and invalidity contentions for patent cases arising under the Hatch-Waxman Act’”).

Further, parties are to “proceed with diligence in amending those contentions when new information comes to light in the course of discovery.” *Phigenix, Inc. v. Genentech, Inc.*, 783 F. App’x 1014, 1016 (Fed. Cir. 2019) (quoting *O2 Micro Int’l Ltd. v. Monolithic Power Sys., Inc.*, 467 F.3d 1355, 1365-66 (Fed. Cir. 2006)). In particular, the “spirit of the patent local rules . . . is

to ensure early crystallization of the parties' theories, and specifically, to *place the burden on the plaintiff* to quickly decide on and disclose the contours of its case." *Karl Storz Endoscopy-Am., Inc. v. Stryker Corp.*, No. 14-CV-00876-RS(JSC), 2017 WL 3873622, at *2 (N.D. Cal. Sept. 5, 2017) (emphasis added). The Patent Rules are thus more stringent than the rules that govern the amendment of pleadings and discovery generally, and are intended to prevent the "vexatious shuffling of positions" that could occur if the parties are permitted to freely modify their infringement contentions at any point in the action." *Berger*, 2006 WL 1095914, at *3.

Under the District of New Jersey's Local Patent Rules, Plaintiffs were required to provide "a chart identifying specifically where each limitation of each asserted claim is found within each Accused Instrumentality" and "[a]ll documents or things that a party asserting patent infringement intends to rely on in support of any of its infringement contentions under these Rules." L. Pat. R. 3.1(c), 3.2(f).

"Infringement contentions . . . serve the purpose of providing notice to the Defendants of infringement theories beyond the mere language of the patent claim." *Intellectual Ventures I LLC v. AT&T Mobility LLC*, No. CV 13-1668-LPS, 2017 WL 658469, at *2 (D. Del. Feb. 14, 2017); *see also Connectel, LLC v. Cisco Sys., Inc.*, 391 F. Supp. 2d 526, 528 (E.D. Tex. 2005). "[A] plaintiff is required to include in its infringement contentions all facts known to it, including those discovered in its pre-filing inquiry." *Shared Memory Graphics LLC v. Apple, Inc.*, 812 F. Supp. 2d 1022, 1024 (N.D. Cal. 2010). Plaintiffs may not "alter their infringement theory after it [becomes] apparent that they [are] going to lose." *Berger*, 2006 WL 1095914, at *6.

When patentees fail to properly disclose their theories of infringement, courts have excluded those theories, as well as any expert reports and related materials that flow from them. *See Phigenix, Inc.*, 783 F. App'x at 1018 (affirming N.D. Cal. court's decision to strike expert

report when plaintiff's infringement theory diverged from the theory presented in infringement contentions); *see also MLC Intellectual Property, LLC v. Micron Technology, Inc.*, 14-cv-03657-SI, 2019 WL 1865921, at *7 (N.D. Cal. 2019) (granting motion to strike portions of expert report based on new theories not included in infringement contentions); *King Pharms.*, 2010 WL 2670804, at *1 (striking portions of expert reports that relied on package inserts not identified in infringement contentions). In short, as contemplated by the Local Patent Rules and Rule 37 of the Federal Rules of Civil Procedure, a plaintiff's failure to adequately disclose its New Infringement Theories under Local Patent Rules requires exclusion of those theories.

IV. THE MAGISTRATE JUDGE'S ORDER DENYING DEFENDANTS' MOTION SHOULD BE REVERSED AND PLAINTIFFS' EXPERT REPORTS SHOULD BE STRICKEN.

A. The Magistrate Judge Erred By Denying Defendants' Motion To Strike The Portion Of Plaintiffs' Reports That Relyed On The Janssen Product.

Plaintiffs' experts relied on a previously undisclosed comparison between Zydus's and MSN's Accused Products and the Janssen Product, including by using multiple documents that had not been disclosed in the Contentions. The Magistrate Judge denied Defendants' motion to strike those new infringement theories from the Reports, because cases "evolve," and because Defendants were purportedly put on notice by Plaintiffs' production of the samples, even though they were produced after the close of fact discovery:

As to the Janssen relevancy argument, the Court believes this is a red herring. Cases evolve, and by producing its samples, plaintiffs implicitly, if not explicitly, represented that the samples were relevant to the issues in the case.

(Ex. OO, Tr. at 44:11-15.)

There are two errors in this reasoning. First, the Magistrate misapplied the law, as the Local Patent Rules are designed precisely to prevent Plaintiffs' infringement theories from "evolving" in this way. *King Pharm.*, 2010 WL 2015258, at *4 ("The [Local Patent Rules] are

designed to require parties to crystallize their theories of the case early in the litigation and to adhere to those theories once they have been disclosed.”). Second, the Magistrate Judge both misapplied the law and misapprehended the facts, as a mere production of samples does not serve to “disclose” Plaintiffs’ New Infringement Theory, especially when that production was repeatedly coupled with statements that the samples were irrelevant. (Exs. GG, HH.)

1. The Local Rules Discourage Trial By Surprise

As the Magistrate Judge recognized, Plaintiffs’ infringement theory has “evolve[d]” since they served their Infringement Contentions in mid-2018. This evolution of Plaintiffs’ case represents exactly the kind of “vexatious shuffling of positions” that the Local Patent Rules are meant to prevent. *See Berger*, 2006 WL 1095914 at *3.

Plaintiffs’ Infringement Contentions nowhere disclosed that Plaintiffs intended to rely on a comparison to Janssen’s own products or samples. (*See* § II.B, above.) Nor did Zydus and MSN have any reason to believe Plaintiffs would somehow change course and rely heavily on their own embodiment. Plaintiffs repeatedly refused to produce samples of the Janssen Product on the basis that they were “neither relevant to any claim or defense currently in this action.” (Ex. HH at 1; *see* § II.D). Indeed, proving infringement through a comparison to the purported commercial embodiment is disfavored. *See, e.g., Zenith Labs., Inc. v. Bristol-Myers Squibb Co.*, 19 F.3d 1418, 1423 (Fed. Cir. 1994) (“[I]t is error for a court to compare in its infringement analysis the accused product or process with the patentee’s commercial embodiment or other version of the product or process; the only proper comparison is with the claims of the patent.”).

Thus, while the Magistrate Judge correctly recognized the facts – Plaintiffs’ theories have evolved since they served their Contentions – he incorrectly applied the law. Infringement theories must be disclosed in Infringement Contentions and in discovery responses, and failure to

do so means “the party is not allowed to use that information . . . to supply evidence . . . at a trial.” L. Pat. R. 3.2; Fed. R. Civ. P. 37(c)(1). Plaintiffs’ failure to disclose their infringement theories when required by the Local Patent Rules means that those theories, and the Expert Reports relating to them, must be stricken. *Phigenix, Inc.*, 783 F. App’x at 1018 (affirming exclusion of expert report in light of changes to infringement theory). The Magistrate Judge’s decision to the contrary is a misapplication of the law and should be reversed. *See, e.g., Gunter*, 32 F. Supp. 2d at 164 (recognizing that reversal is appropriate where a magistrate has misapplied the applicable law).

2. Plaintiffs’ Late Production Of Samples – They Previously Refused to Produce – Is Not Equivalent To Disclosure Of Their Infringement Theories

Nor does Plaintiffs’ belated production – after the close of fact discovery – of the Janssen Product somehow cure their failure to include this New Infringement Theory in their Contentions. The Magistrate Judge made a factual finding that Plaintiffs’ disclosing of samples of the Janssen Product was tantamount to Plaintiffs’ declaration that the samples are relevant to the issues in this case. But, as an initial matter, a concession of relevancy (which Plaintiffs’ production was not) is not tantamount to the timely disclosure of Plaintiffs’ infringement theory. Indeed, Plaintiffs made no representations during the course of two years of discovery, or even afterwards, that they intended to heavily rely upon comparisons of the Janssen Product against the Accused Products to prove infringement.

Nonetheless, even if the samples were “relevant” to the case, it was a misapplication of the law to find that Plaintiffs had somehow cured their failure to include their new infringement theory based on comparisons to the Janssen Product in their Infringement Contentions. Certainly, the circumstances surrounding Plaintiffs’ production of the Janssen Product – after the

close of fact discovery, no less – did not rise to the level of disclosure required by the Local Patent Rules. *See Shared Memory Graphics*, 812 F.Supp. 2d at 1024 (noting that plaintiffs must include “all facts known” in infringement contentions).

In any event, the Magistrate Judge’s factual finding is clearly erroneous for the additional reason that it is flatly contradicted by all of the evidence on record. Plaintiffs affirmatively took the position that Janssen’s Product was not relevant to their claims against Defendants, and repeatedly refused to produce samples. (*See* § II.D above, Exs. GG, HH.) When they did finally agree to produce samples in November 2019, they stated that it was done “in the spirit of compromise” to end an ongoing discovery dispute (Exs. JJ, KK.) Contrary to the Magistrate Judge’s conclusions, there was no hint that the samples were relevant to the case at all, much less to Plaintiffs’ infringement theories.

Through at least July of 2019, Plaintiffs maintained that the Janssen Product was not relevant to the case and continued to refuse to produce samples. (*See* § II.D, above.) Plaintiffs should be required to adhere to those representations: according to the Local Patent Rules, Plaintiffs were obligated to have crystallized their infringement theories months earlier when they served their Infringement Contentions. *See, e.g., King Pharm.*, 2010 WL 2015258, at *4 (noting requirement that parties “crystallize their theories of the case early in the litigation”). Plaintiffs should not be allowed to benefit from delaying until after the close of fact discovery their “disclosure” that the Janssen Product was, in fact, relevant to their infringement theories (to the extent their production could be construed as such a disclosure).

Further, when Plaintiffs finally produced their samples in December 2019, they did so only “in the spirit of cooperation” to avoid further discovery disputes, and did not simultaneously request to amend their Infringement Contentions or supplement their written discovery

responses, *i.e.* there was no representation to Defendants, either explicitly or implicitly, that these samples were now a critical, much less “relevant” part of Plaintiffs’ case, contrary to the Magistrate’s conclusion. (Ex. OO, Tr. at 44:12-15 (“[B]y producing its samples, plaintiffs implicitly, if not explicitly, represented that the samples were relevant to the issues in the case.”)).

And with Plaintiffs’ belated production, almost four months after the close of fact discovery and barely more than a month before the initial exchange of Expert Reports, Defendants were significantly prejudiced in their ability to respond to any use of Plaintiffs’ samples, even if Defendants somehow guessed that Plaintiffs now intended to use their own samples as part of their infringement theory. (*See* § IV.C below.) Defendants should not be penalized for taking Plaintiffs’ at their word and failing to anticipate infringement theories that rely on samples that Plaintiffs repeatedly refused to produce, claiming they were not relevant. *Cf. Read*, 397 F. Supp. 3d at 648-49 (stating that a party who fails to disclose has the burden to show that such failure was justified and harmless). (*See also* Ex. CC at 8:21-22 (“[T]he Court is not going to put the burden on plaintiff to point out to the defendant the deficiencies in their contentions.”).) The Expert Reports or portions thereof that rely on the use of the Janssen samples as reference standards should be stricken.

B. The Magistrate Judge Erred When He Did Not Strike The Portion Of Plaintiffs’ Expert Reports That Relyed On Undisclosed Testing Methodologies.

The Magistrate Judge erroneously denied Defendants’ motion to strike the portions of Plaintiffs’ Expert Reports that relied on previously undisclosed testing methodologies used to show infringement, on the basis that: (1) Plaintiffs’ Infringement Contentions adequately disclosed their new infringement theories (despite only referencing XRPD testing), in part based upon the determination that further disclosure would violate the work product doctrine, and (2)

Defendants filed their motion too late because they were supposedly on notice of the dispute regarding Plaintiffs' disclosure of their infringement theories as of August 2018. The Magistrate Judge's reasoning was clearly erroneous and contrary to law on both counts.

1. Disclosure of Plaintiffs' Contentions Would Not Reveal Work Product

Plaintiffs' Infringement Contentions provide only that “[t]esting will show” that Defendants' products infringe the '582 patent, and disclosed only XRPD testing. The Magistrate Judge concluded that this disclosure was sufficient with respect to all the newly disclosed tests upon which Plaintiffs' new infringement theories relied in Plaintiffs' Expert Reports: “plaintiffs' contentions were complete when made” because they “specifically stated that they would rely on testing to be conducted in the future.” (Tr. at 39:13-23.) The Magistrate Judge further opined that any additional disclosures would have required Plaintiffs to produce privileged “work product.” (*Id.*)

Plaintiffs' Infringement Contentions, however, did not disclose any of the following testing methodologies upon which most of the challenged experts almost exclusively relied:

- ¹⁹F ssNMR testing (*see* Ex. A, Trout Zydus Report at ¶¶ 125-32, 150-54; Ex. F, Trout MSN Report at ¶¶ 131-138, 150-154; *see generally* Ex. B, Munson Zydus Report at ¶¶ 97-169; Ex. G, Munson MSN Report at ¶¶ 95-162);
- Polarized light microscopy (*see* Ex. A, Trout Zydus Report ¶ 114; Ex. F, Trout MSN Report at ¶¶ 113; *see generally* Ex. D, Blatter Zydus Report at ¶¶ 40-42; Ex. I, Blatter MSN Report at ¶¶ 40-43);
- Raman spectroscopy, including FT Raman and microspectroscopy (*see, e.g.*, Ex. A, Trout Zydus Report ¶¶ 86, 115-24; Ex. F, Trout MSN Report at ¶¶ 122-130; *see generally* Ex. D, Blatter Zydus Report at ¶¶ 43-65; Ex. I, Blatter MSN Report at ¶¶ 44-69); and
- Synchrotron-XRPD testing (*see, e.g.*, Ex. A, Trout Zydus Report ¶¶ 137-44; Ex. f, Trout MSN Report at ¶¶ 114-121, 143-149; *see generally* Ex. E Behets Zydus Report at ¶¶ 20-

29; Ex. C, Gozzo Zydus Report at ¶¶ 19-30; Ex. J, Behets MSN Report at ¶¶ 20-29; Ex. H, Gozzo MSN Report at ¶¶ 19-30).

Plaintiffs' Contentions and their vague reference to some undefined "testing" cannot be said to adequately give Defendants notice of the New Testing Methodologies listed above. There are dozens of different tests that Plaintiffs could have chosen to use (see § II.B, above.), and Defendants had no way to prophesize which ones Plaintiffs would ultimately rely upon. Where, as here, a party fails to disclose its infringement theories, the proper remedy is that expert reports relying on those theories be stricken. *See, e.g.*, Fed. R. Civ. P. 37; *see also MLC Intellectual Property*, 2019 WL 1865921, at *7 (granting motion to strike portions of expert report based on undisclosed infringement theories); *King Pharms.*, 2010 WL 2670804, at *1 (same). The Magistrate Judge recognized this explicitly in the order on Plaintiffs' earlier motion to strike portions of Defendants' invalidity expert reports:

It is clear, therefore, that a party may not amend its contentions and produce documents and/or identify documents that must otherwise be produced and/or identified pursuant to Local Patent Rule 3.4 via an expert report. It is also clear that if an expert report impermissibly attempts to amend a party's contentions, the relevant portions of the expert report must be stricken. . . . [A] party cannot circumvent the local rules by including in expert reports what should have been included in a part[y]'s contentions.

(Ex. DD at 6:17-7:3.) Indeed, the Magistrate Judge made clear that this same principal applies equally to infringement contentions. (*Id.* at 26:1-12.) Yet, the Magistrate Judge erroneously failed to apply this standard when ruling on Defendants' motion below.

Moreover, the Magistrate Judge erroneously concluded that the four New Methodologies were properly disclosed when the Plaintiffs "disclosed that plaintiffs would rely on tests to be conducted in the future." (Ex. OO, Tr. at 40:18-19.) But if that were true, any Plaintiff could simply state that "testing will show" infringement, instead of providing actual contentions. *See*

Intellectual Ventures I LLC, 2017 WL 658469, at *2 (noting that it is not sufficient to restate the patent claim). That is the exact situation that the Local Patent Rules were enacted to prevent. Here, the only methodology actually disclosed was XRPD, and the Magistrate’s finding that the New Testing Methodologies were somehow inherently disclosed was clearly erroneous and contrary to the Local Patent Rules.

The Magistrate Judge also misapplied the work product doctrine. The Local Patent Rules require that Plaintiffs identify “specifically where each limitation of each asserted claim is found within each Accused Instrumentality.” L. Pat. R. 3.1(c). Case law is clear that contentions must include more than “the mere language of the patent claim.” *Intellectual Ventures I LLC*, 2017 WL 658469, at *2. “Plaintiff must . . . articulate the precise way in which it believes the products to be infringing.” *Tessanderlo Kerley, Inc. v. OR-Cal, Inc.*, No. C 11-04100 WHA, 2012 WL 1253178, at *4 (N.D. Cal. Apr. 13, 2012). (“To the extent testing data are the basis for this belief, this order finds its disclosure is required under Rule 3-1.”). Thus, contentions must disclose the **factual basis** for a plaintiff’s infringement theories, not simply recite the claim limitations of the asserted patent (or say that “testing will show” infringement).

And germane to the circumstances here, courts have found that testing data must be disclosed during the contentions stage and are not protected by the work-product doctrine. *Tessanderlo*, 2012 WL 1253178, at *3-4 (rejecting the argument that test data is protected from disclosure under the attorney work-product doctrine); *Tillotson Corp. v. Shijiazhaung Hongray Plastic Prod., Ltd.*, 244 F.R.D. 683, 693 (N.D. Ga. 2007) (requiring plaintiff to disclose testing data “to the extent that the test data supports any of the plaintiff’s contentions”); *Kimberly-Clark Worldwide, Inc. v. First Quality Baby Prod., LLC*, No. 1:CV-09-1685, 2010 WL 4537002, at *2-3 (M.D. Pa. Nov. 3, 2010) (testing data not subject to work-product protection; “to the extent that

[plaintiff] relies on the factual information acquired from any testing, . . . plaintiff must disclose that information even if it requires separating mental impressions from factual information"). And certainly if test data itself must be disclosed, there can be no credible argument that the identification of the specific methodologies to generate that data can be withheld on the basis of the work-product doctrine. Consequently, despite the Magistrate Judge's erroneous application of the law, Plaintiffs cannot rely on the work product doctrine to shield the disclosure in contentions of testing methodologies that are later going to be relied upon in expert reports.

2. Defendants Could Not Have Challenged Plaintiffs' Expert Reports Before The Reports Were Served

Second, the Magistrate Judge also erred when it held that Defendants should have challenged Plaintiffs' theories earlier, when Plaintiffs served their contentions. Defendants' motion to strike did not (and does not) challenge the sufficiency of Plaintiffs Infringement Contentions, which disclosed using XRPD testing. Rather, Defendants are challenging the Expert Reports that introduced New Infringement Theories that were not disclosed in those Contentions. Under the law, including Federal Rule of Civil Procedure 37(c)(1), Plaintiffs must be restricted at trial to relying only on the theories disclosed during discovery. *See King Pharm.,* 2010 WL 2670804, at *1 (striking portions of expert reports that relied on infringement theory not identified in infringement contentions). Until Defendants received Plaintiffs' Expert Reports, they could not have been aware of the new theories that were being asserted and could not have known that they would need to seek relief from the Court.

Given that Plaintiffs chose to only disclose XRPD testing, their lack of specificity should be to their detriment, not Defendants.' *See, e.g., Read,* 397 F. Supp. 3d at 648-49 (noting that party who failed to disclose has the burden to show that its failure was justified or harmless); *cf. M. Eagles Tool Warehouse, Inc.,* 2007 WL 979854, at *12 (noting that exclusion of evidence

pursuant to Rule 37 is meant to induce appropriate disclosures of information). Plaintiffs' Expert Reports should be stricken to the extent they present information that should have, and could have, been included in Plaintiff's Infringement Contentions. *See, e.g., Phigenix, Inc.*, 783 F. App'x at 1018 (affirming exclusion of expert report in light of changes to infringement theory).

C. Defendants Have Been Prejudiced by Plaintiffs' Failure To Timely Disclose Their Infringement Theories, Contrary To The Magistrate Judge's Erroneous Finding.

Finally, any late disclosure of infringement theories is inherently prejudicial. Plaintiffs failed to even identify which other analytical methods they *might* use for their infringement theories, thereby inflicting severe prejudice on Defendants' ability to prepare their defense. *See Phigenix*, 783 F. App'x at 1017 (noting that a significant change to the infringement theory at "a late stage in the litigation . . . 'markedly transformed the nature of the infringement theory, and consequently, impacted [the alleged infringer's] ability to prepare a defense'"'); *see also Adobe Sys. Inc. v. Wowza Media Sys.*, No. 11-CV-02243-JST, 2014 WL 709865, at *15 n.7 (N.D. Cal. Feb. 23, 2014) (stating that "prejudice is inherent in the assertion of a new theory after discovery has closed" and pointing out the "incentive for late disclosure" if such prejudice is permitted).

Where, as here, a defendant is deprived of adequate information about the infringement theories asserted against it, that defendant is likewise deprived of the opportunity to tailor its discovery to those theories. *See, e.g., Galderma Labs., L.P. v. Amneal Pharms., LLC*, No. 16-207-LPS, 2018 WL 508876, at * 2 (D. Del. Jan. 22, 2018) (denying motion to amend infringement contentions where delay deprived defendant of the opportunity to "take [a] different approach to . . . discovery" and defendant was forced to "scramble to have an expert respond").⁷

⁷ Plaintiffs complained below that several of the cases cited by Defendants are inapposite because they address striking or amending infringement contentions, rather than solely motions to strike expert reports. But these cases show what sort of disclosure is expected in contentions,

The Magistrate Judge incorrectly ruled that Defendants were not prejudiced by Plaintiffs failure to disclose their New Infringement Theories because (1) the tests conducted by Plaintiff are “standard in the industry”; (2) Defendants will be able to cross-examine Plaintiffs’ experts at trial and Defendants have adequate time to prepare their defense and witnesses prior to trial; (3) Defendants’ “delay” in seeking the Court’s assistance shows that the information was not important; (4) other defendants failed to join in Defendants’ motion; and (5) Defendants did not ask for additional time to respond to Plaintiffs’ Expert Reports. (Tr. at 42:16-43:18.) All of these reasons are contrary to the law and the facts of this case, and the Court should set aside the Magistrate Judge’s prejudice determination. *See Fed. R. Civ. P. 72(a)* (“The district judge in the case must consider timely objections and modify or set aside any part of the order that is clearly erroneous or is contrary to law.”).

First, the Magistrate’s finding that the tests Plaintiffs conducted were “standard in the industry” and “known to defendants” (Ex. OO, Tr. at 42:19-21) misapprehends that there are *dozens* of additional methodologies that Plaintiffs could have possibly used to test the Accused Products. (*See* n.7, above.) Indeed, when asked to identify “the analytical testing Plaintiffs contend is the most appropriate to identify and distinguish among” forms of canagliflozin,” Plaintiffs identified over twenty different tests. (*See id.*) The Magistrate Judge seems to suggest that Defendants should have identified and retained multiple experts with specialized testing capability in dozens of different areas, and been prepared to conduct dozens of purportedly “standard” tests, depending on what infringement theories Plaintiffs finally decided to disclose

and provide guidance on prejudice. Further, Plaintiffs themselves relied on case law concerning contentions in their own letter motion to strike portions of Defendants’ invalidity expert reports, Plaintiffs themselves cite law regarding motions to amend contentions and the risk of prejudice due to “eleventh-hour alterations.” (ECF No. 280 at 11 (*citing CBS Interactive, Inc. v. Etilize, Inc.*, 257 F.R.D. 195, 203 (N.D. Cal. 2009).)

months after the end of fact discovery. Thus, regardless of whether a test was generally known to Defendants, Defendants at best would have had to incur thousands upon thousands of dollars in speculative testing and retention of experts in myriad testing methodologies, with no guarantee that *any* of those costs would ever provide any benefit to Defendants' case.

Further, aside from the cost, even tests that are known or "standard" are not necessarily easy to conduct, especially on short notice. Plaintiffs relied on experts from all over the world who used specialized equipment. For example, Dr. Behets conducted synchrotron-XRPD testing at the European Synchrotron Radiation Facility (ESRF). (Ex. E (Behets Report) at ¶ 13.) The application process and preparation for running experiments at ESRF require a significant amount of effort.⁸ It would have been extremely challenging, if not impossible for Zydus and MSN to (1) identify and retain experts who could conduct all the tests performed by Plaintiffs' experts in the immediate future, (2) work with those experts to determine what experiments should be conducted on which samples, and (3) gain access to facilities with the correct specialized equipment to actually perform the experiments, assuming that the specialized equipment was even available on such short notice. The Magistrate Judge's finding on this point was based on a clearly erroneous view of the facts.

Second, Defendants' ability to prepare for trial and cross-examine Plaintiffs' witnesses cannot make up for Defendants' inability to shape their strategy during discovery. *See, e.g., Galderma*, 2018 WL 508876, at *2 (denying motion to amend infringement contentions where delay deprived defendant of the opportunity to "take [a] different approach to . . . discovery" and was forced to "scramble to have an expert respond"); *see also Golden Hour Data Sys., Inc. v.*

⁸ *See, e.g.*, Ex. MM (the ESRF's procedures for booking beamtime for synchrotron-XRPD testing), available at <https://www.esrf.eu/cms/live/live/en/sites/www/home/Industry/our-services/book-beamtime.html>.

Health Servs. Integration, Inc., No. C 06-7477 SI, 2008 WL 2622794, at *4 (N.D. Cal. July 1, 2008) (“The Patent Local Rules were designed, among other reasons, to prevent the parties from shifting their theories late in discovery, leaving the opposing party with little time to conduct discovery on a new theory.”). If Defendants had been made aware of the tests that Plaintiffs intended to conduct, they could have questioned Plaintiffs’ fact witnesses about those tests, potentially securing helpful testimony. The Magistrate Judge’s reliance on Defendants’ ability in the future to prepare for trial is contrary to the law and ignores that trial preparation does not enable Defendants to redo fact discovery.

Third, as explained above in Section IV.B, Defendants did not delay applying to the Court for assistance. Defendants are not challenging Plaintiffs’ Infringement Contentions, but are rather challenging the parts of the Expert Reports that introduced New Infringement Theories beyond what had been previously disclosed. Defendants could not have anticipated beforehand which specific testing methodologies Plaintiffs would rely on to show infringement.

Fourth, the Magistrate Judge gave undue attention to other defendants’ decisions not to join Zydus and MSN’s motion, concluding that this showed a lack of prejudice to defendants. This conclusion was based on several clear errors. As an initial matter, the Magistrate’s finding rests on an assumption that the other defendants faced the same or similar issues. But there was no evidence before the Court about what information was, or was not, in the infringement contentions or expert reports directed to the other defendants. Nor have Defendants seen any of the other infringement reports. Thus, neither Defendants nor the Magistrate Judge could have determined whether the other defendants were, in fact, similarly situated.⁹

⁹ While Plaintiffs claimed, at the hearing, that the other expert reports presented theories that “[w]ere the same exact or essentially the same positions set forth” with respect Zydus and

And it appears that at least three out of the other four defendants *were not* similarly situated: Sandoz stipulated to infringement on February 11, 2020, and Aurobindo and Laurus have since settled with Plaintiffs. (ECF Nos. 270, 329, 350.) If these defendants were considering or discussing settlement, or otherwise did not challenge infringement, it is understandable that they would not wish to incur the costs of a discovery dispute that would be irrelevant to them. Regardless, any speculation into tactical decisions made by other defendants is not based on the evidence in the record and should not be held against Zydus and MSN.

Fifth, the Magistrate Judge essentially penalized Defendants for managing to complete a responsive expert report in the time allotted.¹⁰ As noted in *Galderma*, Defendants' ability to produce a fulsome responsive report does not negate the fact that Defendants were presented with six expert reports with no warning: "there is no way to know whether [the expert's opinions] are the same as they would have been" if Plaintiffs had properly disclosed their infringement theories. 2018 WL 508876, at *2. And with respect to Defendants' "failure" to seek more time to respond to the Expert Reports, the Magistrate Judge does not appear to have considered that Defendants, in contrast to Plaintiffs, have an interest in moving quickly in this litigation. At the time Defendants responded to Plaintiffs' Expert Reports, trial was scheduled for June 2020 (ECF No. 243) and Defendants had a significant interest in ensuring that the case continued to progress at pace, because a delay in trial potentially means a delay in coming to market.¹¹ If a plaintiffs' claims are not resolved before the expiration of the 30-month

MSN, Defendants cannot address or rebut this statement, and thus it is inappropriate to rely on Plaintiffs' representations. (Ex. OO, Tr. at 8:5-12.)

¹⁰ The parties did agree to a one-week extension.

¹¹ At this time the COVID-19 pandemic had scarcely hit the United States, and there was no indication of the many delays that it would eventually impose.

automatic stay, a defendant must either delay marketing, or risk increased damages from marketing without certainty from a court that their accused products do not infringe. *See* 21 U.S.C. §355(j)(5)(B)(iii) (stating that approval of an ANDA shall be effective at the end of 30-month stay). In addition, Defendants understood that this Court was not inclined to move the deadline for expert discovery, which was originally set for May 7, 2020.¹² (*See* ECF No. 279.)

Moreover, the Magistrate Judge failed to recognize that an extension of a few weeks, or a few months, would not have been sufficient to rebut Plaintiffs' Expert Reports, particularly in light of the difficulty of scheduling and performing all the relevant tests.¹³ To fully respond, Defendants would not only have had to identify and retain experts with access to specialized test equipment, who were available immediately, but also schedule time to use the necessary equipment. (*See* p. 27 above.)

In sum, the Magistrate Judge's conclusion that Defendants have not been prejudiced by Plaintiffs' delinquent disclosure is unsupported by the facts of this case or the relevant law.

V. CONCLUSION

For the foregoing reasons, Defendants respectfully request that the Court reverse Magistrate Judge Schneider's May 18, 2020 order denying Defendants' Motion to Strike Plaintiffs' Expert Reports (ECF No. 316).

¹² The due dates for reply expert reports and expert discovery have now shifted on account of the COVID-19 pandemic.

¹³ Indeed, Plaintiffs performed their tests on Defendants' Products over the course of nearly a year and a half. (Ex. U (referencing May 2018 testing date); Ex. C at ¶ 22 (referencing sample preparation in November 2019).)

Dated: June 23, 2020

Respectfully submitted,

By: /s/ Sean R. Kelly
Sean R. Kelly
Katherine A. Escanlar
SAIBER LLC
18 Columbia Turnpike, Suite 200
Florham Park, New Jersey 07932
(973) 622-3333
skelly@saiber.com
kescanlar@saiber.com

Jay R. Deshmukh
Hershy Stern
Jayita Guhaniyogi, Ph.D.
KASOWITZ BENSON TORRES LLP
1633 Broadway
New York, New York 10019
(212) 506-1700
jdeshmukh@kasowitz.com
hstern@kasowitz.com
jguhaniyogi@kasowitz.com

*Attorneys for Defendant
Zydus Pharmaceuticals (USA) Inc.*

By: /s/ James S. Richter

James S. Richter
MIDLIGE RICHTER, LLC
645 Martinsville Road
Basking Ridge, NJ 07920
(908) 626-0622
jrichter@midlge-richter.com

George C. Lombardi
WINSTON & STRAWN LLP
35 W. Wacker Drive
Chicago, Illinois 60611
(312) 558-5600

Jovial Wong
Sharon Lin
WINSTON & STRAWN LLP
1901 L Street NW
Washington, D.C. 20036
(202) 282-5000
jwong@winston.com
slin@winston.com

Attorneys for Defendants
MSN Laboratories Private Ltd. and
MSN Pharmaceuticals, Inc.